REMARKS/ARGUMENTS

With this amendment, claims 1-22 are pending. Claims 3-6, 10, 13, 14, 17, and 19-22 are withdrawn. Claims 23-44 are cancelled without prejudice. For convenience, the Examiner's rejections are addressed in the order presented in an August 4, 2006, Office Action.

I. Status of the claims

Claim 1 is amended to recite a step of determining the in vitro effect of a compound on a FEN1 polypeptide. Support for this amendment is found throughout the specification, for example, at original claim 23. Claim 1 is amended to recite a heterologous FEN1 polypeptide. Support for this amendment is found throughout the specification, for example, at page 31, lines 17-24. Claim 1 is amended to recite 95% identity to a reference FEN1 polypeptide. Support for this amendment is found throughout the specification, for example, at page 21, line 21 through page 22, line 9. Claim 1 is also amended to recite that the determined chemical or phenotypic effect is a cell cycle effect. Support for this amendment is found throughout the specification, for example, at page 23, lines 1-3. These amendments add no new matter.

Claim 2 is amended to recite that the cell cycle effect of a compound is compared to the cell cycle effect of a dominant negative FEN1 polypeptide. Support for this amendment is found throughout the specification, for example, at page 87, line 30 through page 88, line 5 and at Figures 67 and 68. Claim 16 is amended to reflect a species election. These amendments add no new matter.

II. Rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3, 7-9, 11, 12, 15, 16, 18 and 23 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. First, the Office Action objects to use of the phrase "hybridizes under stringent conditions." In order to expedite prosecution, independent claim 1 is now amended to recite 95% identity to a reference sequence. Second, the Office Action alleges that the claims omit an essential step. In order to expedite prosecution, independent claim 1 is

now amended to recite "determining the cell cycle effect of the compound upon the cell comprising the heterologous FEN1 polypeptide, thereby identifying a compound that modulates cell cycle arrest." In view of the above amendments and remarks, withdrawal of the rejections for alleged indefiniteness is respectfully requested.

III. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 1, 3, 7-9, 11, 12, 15, 16, 18 and 23 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the Office Action, the specification does not provide description of the claimed genus of polypeptides encoded by nucleic acids that hybridize to a reference sequence. The Office Action alleges that those of skill would not recognize that the inventors had possession of the claimed invention at the time of filing. The claims are now amended to recite FEN1 polypeptides that have 95% identity to a reference sequence and are used to identify modulators of the cell cycle. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

As currently applied, the specification does comply with US patent law for description of a nucleic acid or amino acid sequence. The Federal Circuit court of Appeals addressed the description adequate to show one of skill that the inventors were in possession of a claimed genus at the time of filing. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). An applicant may also show that an invention is complete by

> . . . disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Id.* at 1613.

Furthermore, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *See, e.g.*, 66 Fed. Reg. 1099, 1106 (2001).

Functional assays to identify FEN1 polypeptides, as recited in the claims, were known to those of skill and are disclosed in the specification. FEN1 assays are disclosed in the specification at, *e.g.*, page 16, lines 12-16 and page 81, lines 4-9.

Applicants respectfully bring to the Examiner's attention two recent decisions by the Board of Patent Appeals and Interferences: *Ex parte Sun,* Appeal No. 2003-1993 and *Ex parte Bandman*, Appeal No. 2004-2319. In both cases, the board found that claims directed to sequences with 80% or 95% identity to a reference sequence were described because the supporting specifications provided a single reference sequence, teachings of areas of the claimed sequences that could be modified, and a functional assay for activity of the encoded proteins. Such teachings are included in the present application, as indicated above.

Applicants also direct the Examiner's attention to Example 14 of the Synopsis of Application of Written Description Guidelines which analyzes a claim directed to a protein having an amino acid sequence at least 95% identical to SEQ ID NO:3 and that has a specific activity. In these Guidelines, the Patent Office concluded that the claim was adequately described within the meaning of 35 U.S.C. §112, first paragraph. The FEN1 protein does have an enzymatic activity as discussed in the specification at, *e.g.*, page 16, lines 12-16 and page 81, lines 4-9. Therefore, on the basis of Written Description Guidelines issued by the USPTO, the present claims directed to FEN1 polypeptides that are 95% identical to SEQ ID NO:14, meet the written description requirement.

In view of the above arguments and amendments, withdrawal of the rejection for alleged lack of written description is respectfully requested.

IV. Rejections under 35 U.S.C. §102(b)

Claims 1, 2, 7, 8, 9, 11, 12, 15, 16, 18 and 23 are rejected as allegedly anticipated by either Harrington *et al.* (US Patent No. 5,874,283), or by Bai *et al.*, (*FEBS Letts.*, 437:61-64 (1998)). To the extent the rejections apply to the amended claims, Applicants respectfully traverse the rejections.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found...in a single

prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, in order to anticipate, the cited references must contain every element of the claims at issue. The cited references do not.

A. Harrington et al.

Claims 1, 2, 7, 8, 15, 16, 18 and 23 are rejected as allegedly anticipated by Harrington *et al.* According to the Office Action, Harrington *et al.* discloses methods for identifying agents that modulate the FEN1 protein. Applicants assert that Harrington *et al.* does not disclose all the element of the amended claims. Independent claim 1 requires determination of the cell cycle effect of a heterologous FEN1 protein on a cell comprising that protein in order to identify a compound that modulates cell cycle arrest. Harrington *et al.* does not disclose determination of a cell cycle effect, including cell cycle arrest, on a cell that comprises a heterologous FEN1 protein. In addition, dependent claim 2 now requires comparison of the cell cycle effect the compound to the cell cycle effect of a dominant negative FEN1 mutant polypeptide. Harrington *et al.* provides no disclosure of mutant FEN1 proteins, including dominant negative FEN1 proteins. Therefore, Harrington *et al.* does not disclose all the elements of the claims and cannot anticipate the claimed invention.

B. Bai et al.

Claims 1, 9, 11, and 12 are rejected as allegedly anticipated by Bai *et al.* According to the Office ActionA549 cell inherently express FEN1 protein and Bai *et al.* discloses treatment of A549 cells with a molecule that inhibits cellular proliferation. However, as amended claim 1 now requires determination of the effect of a compound on the FEN1 protein in vitro. Bai *et al.* does not disclose an in vitro analysis of FEN1 activity. For cell-based assays, claim 1 now requires use of cells that comprise a heterologous FEN1 protein. Bai *et al.* does not disclose cells that comprise a heterologous FEN1 protein. Bai *et al.* does not disclose all the elements of the claims and, thus, cannot anticipate the claimed invention.

In view of the above amendments and remarks, withdrawal of the rejections for alleged anticipation is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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